

PART III: CONSUMER INFORMATION

MYLAN-SUMATRIPTAN (sumatriptan succinate tablets)

This leaflet is part III of a three-part "Product Monograph" published when Mylan-Sumatriptan Tablets was approved for sale in Canada and is designed specifically for Consumers. (Please read this leaflet carefully before you take Mylan-Sumatriptan Tablets). This provides a summary of the information available on your medicine. This leaflet will not tell you everything about Mylan-Sumatriptan Tablets. Please do not throw away this leaflet until you have finished your medicine. You may need to read it again. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

The name of your medicine is Mylan-Sumatriptan (sumatriptan succinate) Tablets. They can be obtained only by prescription from your doctor. The decision to use Mylan-Sumatriptan Tablets is one that you and your doctor should make jointly, taking into account your individual preferences and medical circumstances. If you have risk factors for heart disease (such as high blood pressure, high cholesterol, obesity, diabetes, smoking, strong family history of heart disease, or you are postmenopausal or a male over 40), you should tell your doctor, who should evaluate you for heart disease in order to determine if Mylan-Sumatriptan Tablets are appropriate for you.

What the medication is used for:

Mylan-Sumatriptan Tablets are intended to relieve your migraine headache and other associated symptoms of a migraine attack. **Mylan-Sumatriptan Tablets should not be used continuously to prevent or reduce the number of attacks you experience. Use Mylan-Sumatriptan Tablets only to treat an actual migraine headache attack.**

What it does:

Migraine headache is believed to be caused by a widening of the blood vessels in the head. Mylan-Sumatriptan narrows these vessels and relieves the symptoms of migraine headache.

When it should not be used:

Do not use Mylan-Sumatriptan Tablets if:

- you are allergic to sumatriptan or to any of the ingredients in Mylan-Sumatriptan Tablets. (See "What the nonmedicinal ingredients are:")
- you have a history, or any symptoms or signs of a heart condition
- you have high blood pressure
- you are taking or have recently taken (within 2 weeks) a monoamine oxidase inhibitor (MAOI)
- you are taking or have recently taken (within 24 hours) an ergotamine containing medication or its derivatives, or another triptan used to treat migraine
- you have any degree of liver disease

Mylan-Sumatriptan Tablets should **not** be used for the treatment of other types of headaches that are different from migraine attacks.

What the medicinal ingredient is:

Sumatriptan succinate

What the nonmedicinal ingredients are:

Croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, hydroxypropyl methylcellulose, titanium dioxide, polydextrose, triacetin, polyethylene glycol, synthetic yellow iron oxide (100 mg only) and synthetic red iron oxide (100 mg only).

What dosage form it comes in:

25 mg: White to off-white, round film-coated tablets debossed "G" on one side and "SU25" on the other side. Blister packs containing 6 tablets.

50 mg: White to off-white, triangular-shaped film-coated tablets debossed "G" on one side and "SU50" on the other side. Blister packs containing 6 tablets.

100 mg: Pink, triangular-shaped film-coated tablets debossed "G" on one side and "SU100" on the other side. Blister packs containing 6 tablets.

WARNINGS AND PRECAUTIONS

BEFORE you use Mylan-Sumatriptan Tablets talk to your doctor or pharmacist if:

- you are pregnant, think you might be pregnant, you are trying to become pregnant, you are using inadequate contraception, or you are breast-feeding
- **you have any chest pain, heart disease, shortness of breath, or irregular heartbeats, you have had a heart attack, or you have angina.**
- **you have risk factors for heart disease (such as high blood pressure, high cholesterol, obesity, diabetes, smoking, strong family history of heart disease, or are you postmenopausal or a male over 40).**
- you have ever had to stop taking this or any other medication because of an allergy or other problems, or you are allergic to sulphate-containing drugs
- you are taking any medications, including migraine medications such as other triptans, 5-HT₂ agonists or those containing ergotamine, dihydroergotamine, or methysergide
- you have ever experienced difficulty moving one side of your body when you have a headache
- you have ever had a stroke, transient ischemic attacks (TIAs), or Raynaud's Syndrome
- you are under 18 years of age
- you are over 65 years of age
- you are taking any medication for depression (lithium, monoamine oxidase inhibitors, selective serotonin reuptake inhibitors (SSRIs), or serotonin noradrenaline reuptake inhibitors (SNRIs)?
- you had, or you have any disease of the liver or kidney
- you had, or you have epilepsy or seizures
- this headache is different from your usual migraine attacks

Mylan-Sumatriptan Tablets should not be used continuously to prevent or reduce the number of attacks you experience. Use Mylan-Sumatriptan Tablets only to treat an actual migraine headache attack.

If you use Mylan-Sumatriptan Tablets too often, it may make your headaches worse. If this happens, your doctor may tell you to stop taking Mylan-Sumatriptan Tablets.

The Use of Mylan-Sumatriptan Tablets During Pregnancy:

Do not use Mylan-Sumatriptan Tablets if you are pregnant, think you might be pregnant, are trying to become pregnant, or are not using adequate contraception, unless you have discussed this with your doctor.

INTERACTIONS WITH THIS MEDICATION

Do not use Mylan-Sumatriptan Tablets if you are taking or have recently taken a monoamine oxidase inhibitors (MAOI) in the last 2 weeks, or any migraine medications containing ergotamine, ergot derivatives (such as dihydroergotamine, or methysergide), or other triptans used to treat migraine within 24 hours.

You should tell your doctor if you are taking or have recently taken any other medications (prescription, non-prescription or natural/herbal), before you start taking Mylan-Sumatriptan Tablets, especially any antidepressants such as selective serotonin reuptake inhibitors (SSRIs) and certain tricyclics.

PROPER USE OF THIS MEDICATION

The label on the container of your medicine or the leaflet inside should tell you how often to take a dose and the amount you should take in each dose. If it does not or you are not sure, ask your doctor or pharmacist. **DO NOT** take more medicine or take your medicine more often than you are told.

Usual dose:

Adults: Take as directed by your doctor. If the first tablet does not relieve your headache, do not take further doses of Mylan-Sumatriptan for the same attack. You may take pain medication other than ergotamine-containing preparations for further pain relief. Mylan-Sumatriptan may be taken for subsequent attacks.

Mylan-Sumatriptan tablets can be taken at any time during your migraine headache.

If your symptoms come back, and it has been two hours since your first tablet, you may take a second tablet.

Do not take more than 200 mg in any 24 hour period.

Mylan-Sumatriptan Tablets may be taken with or without food. **The tablet should be swallowed whole with water. It should not be crushed, chewed or split.**

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medications, Mylan-Sumatriptan Tablets can cause some side effects. You may not experience any of them. For most patients these side effects are likely to be minor and temporary. However, some may be serious. Consult your doctor if you experience these or other side effects.

The most commonly reported side effects of sumatriptan succinate tablets are:

- pain, pressure or tightness in any part of the body, including chest and throat
- sensations of heaviness
- unusual sensations including numbness, tingling, heat/burning or cold
- flushing (redness of the face lasting for a short time)
- feeling sick or vomiting
- dizziness
- drowsiness
- tiredness
- weakness

As drowsiness may occur as a result of using Mylan-Sumatriptan succinate tablets, do not drive or operate machinery until you are sure that you are not drowsy.

Other side effects include:

- unusually slow or fast heartbeats, a feeling of irregular and/or forceful heartbeats
- visual disturbances, usually temporary (scotoma, nystagmus, flickering, diplopia).
- Dystonia, (shaking, tremors or uncontrolled movements)
- Loss of normal colouration in the fingers and toes

Tell your doctor of these symptoms at your next visit. Very rarely, some people have reported the following more serious side effects. For information on what to do if you experience these side effects, see the table at the end of this section.

- Pain or tightness in the chest or throat
- Loss of vision
- Shortness of breath; wheeziness; chest tightening; swelling of eyelids, face, or lips; or a skin rash, skin lumps
- a seizure or fit
- sudden and/or severe abdominal pain
- persistent purple discolouration of hands or feet

If you feel unwell in any other way or have any symptoms that you do not understand or find distressing, you should contact your doctor immediately.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Common	Unusual sensations including numbness, tingling, feeling hot or cold; pain, heaviness or pressure in any part of the body including chest and throat	✓		
Very rare	Symptoms of a heart attack [chest pain, sweating, shortness of breath].			✓
Very rare	Unusually slow or fast heartbeats, or a feeling of irregular and/or forceful heartbeats.	✓		
Very rare	Allergic reactions [shortness of breath, sudden wheeziness, chest tightness, swelling of the eyelids, face or lips, lumpy skin rash or hives.			✓
Very rare	Seizures [loss of consciousness with uncontrollable shaking ("fit")]			✓
Very rare	Lower abdominal pain and/or severe rectal bleeding.			✓
Very rare	Raynaud's phenomenon [persistent purple discolouration of hands or feet.]			✓
Very rare	Loss of vision			✓

This is not a complete list of side effects. For any unexpected effects while taking Mylan-Sumatriptan Tablets, contact your doctor or pharmacist.

HOW TO STORE IT

Keep your medicine in a safe place where children cannot reach it. It may be harmful to children.

Keep your tablets in a cool, dry place (15°C to 30°C). If your medication has expired (the expiration date is printed on the treatment pack), throw it away as instructed.

If your doctor decides to stop your treatment, do not keep any leftover medicine unless your doctor tells you to. Throw away your medicine as instructed.

Reminder:

REMEMBER: This medicine is for you. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptoms appear to be similar to yours.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 0701E
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>).

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document can be found at: www.mylan.ca.

The full product monograph prepared for health professionals can be obtained by contacting the sponsor, Mylan Pharmaceuticals ULC, at 1-800-575-1379.

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